PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 4510-1-pct	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US01/21205	International filing date *(day/month/year)* 02 JULY 2001	Priority date *(day/month/year)* 30 JUNE 2000
International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 17/56 and US Cl.: 606/61		
Applicant RITLAND, STEPHEN		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

   - I [X] Basis of the report
   - II [ ] Priority
   - III [ ] Non-establishment of report with regard to novelty, inventive step or industrial applicability
   - IV [ ] Lack of unity of invention
   - V [X] Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI [ ] Certain documents cited
   - VII [ ] Certain defects in the international application
   - VIII [ ] Certain observations on the international application

Date of submission of the demand	Date of completion of this report
08 JANUARY 2002	04 MARCH 2003
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer PEDRO PHILOGENE Telephone No. (703) 308-2252

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US01/21205

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed

☒ the description:
pages (See Attached) , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

☒ the claims:
pages (See Attached) , as originally filed
pages _____ , as amended (together with any statement) under Article 19
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

☒ the drawings:
pages (See Attached) , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

☒ the sequence listing part of the description:
pages (See Attached) , as originally filed
pages _____ , filed with the demand
pages _____ , filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages NONE

☒ the claims, Nos. 2 & 3

☒ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

***Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US01/21205

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	1, 4–37	YES
	Claims	none	NO
Inventive Step (IS)	Claims	1,4–37	YES
	Claims	none	NO
Industrial Applicability (IA)	Claims	1,4–37	YES
	Claims	NONE	NO

2. citations and explanations (Rule 70.7)

Claims 1,4–37 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a surgical implant assembly and a method thereof, comprising a connector having a second end comprising a hollow core , an entry channel and a central aperture operatively associated with the hollow core and the netry channel and an enlarged area including at least one expansion slot and a connecting link having a connecting end with an anchoring shaft cavity the connecting link secured to the connector device by an anchoring shaft nut on the distal end of the anchoring shaft.

NEW CITATIONS

NONE

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

I. BASIS OF REPORT:

This report has been drawn on the basis of the description,
page(s) 1-7, 9-11, 13, 14 & 16, as originally filed.
page(s) NONE, filed with the demand.
and additional amendments:
pages 8, 12 & 15, filed with the letter of 12 AUGUST 2002.

This report has been drawn on the basis of the claims,
page(s) NONE, as originally filed.
page(s) NONE, as amended under Article 19.
page(s) NONE, filed with the demand.
and additional amendments:
pages 17-21, filed with the letter of 12 AUGUST 2002.

This report has been drawn on the basis of the drawings,
page(s) 1-3,5-18, as originally filed.
page(s) NONE, filed with the demand.
and additional amendments:
page 4, filed with the letter of 12 AUGUST 2002.

This report has been drawn on the basis of the sequence listing part of the description:
page(s) NONE, as originally filed.
pages(s) NONE, filed with the demand.
and additional amendments:
NONE

Fig. 19b is a plan view of the surgical implant assembly shown in Fig. 17a.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

With reference to Fig. 1, one embodiment of the attachment device (or connection device) of the present invention is shown in partial cross-section. The attachment device 10 includes a shank 12 having a first end 14 and a second end 16. The first end 14 of the shank 12 includes a securement mechanism 18. As shown in Fig. 1, the securement mechanism 18 may be screw threads. It is noted, however, that the securement mechanism 18 may include any known method of securing one item to another. For example, the securement mechanism 18 may be a hook, a plate, a flange, or adhesive. In the case of the securement mechanism 18 as a flange or plate, the securement mechanism 18 may require additional hardware such as screws, bolts, or adhesive to secure the plate or flange to the intended object. In the case of the securement mechanism 18 as an adhesive, or requiring the additional use of adhesive, the adhesive would necessarily be applied to the securement mechanism 18, not included within it. Additionally, adhesive could be used with the securement mechanism 18, e.g., applied to screw threads, for additional securement capacity.

The second end 16 of the shank 12 generally comprises an enlarged area 20 including a central core 22 and an aperture 24. The second end 16 of Fig. 1 is shown in cross-sectional view to more clearly show the central core 22 and the aperture 24.

With reference to Fig. 2, an embodiment of the second end 16 of the shank 12 is shown. In this embodiment, the enlarged area 20 includes a hollow core 22 and a central aperture 24. The enlarged area also includes an entry channel 26. The entry channel 26 is operatively connected with the hollow core 22 such that a tension link 28, having a shaft 30 with a threaded end 32 and a head end 34, may be inserted, threaded end 32 first, through the entry channel 26, the hollow core 22, and central aperture 24 until the head end 34 of the tension link 28 is retained within the hollow core 22 by the central aperture 24.

With reference to Fig. 3, the embodiment of the second end 16 of attachment device 10 is shown in cross-section. Fig. 3 clarifies the operational relationship between the entry channel 26, the hollow core 22 and the central aperture 24.

With reference to Fig. 4, an alternative embodiment of the attachment device 10 is shown. This embodiment is similar to the embodiment of Figs. 2 and 3, but with an

partial front elevation, in Fig. 10a and Fig. 10b, respectively. Again, this view is "partial" because the thread end 32 of the tension link 28 is omitted from the drawing. The link retainer 44 in this embodiment is a projection that spans the intersection of the shaft 30 and the head end 34 of the tension link 28 and extends partially along the surface of the head end 34. This embodiment may be used in conjunction with the embodiment of the attachment device 10 including the tension link slot 36, as shown in Figs. 4 and 5 above. As in the previous embodiment, the tension link may be prevented from unwanted rotation of the tension link 28 within the hollow core 22. The link retainer 44 may be placed in contact with the wall of the tension link slot 36 to prevent such rotation.

With reference to Fig. 11, an alternative embodiment of the tension link 28 is shown. The tension link 28 again includes a shaft 30 with a head end 34 and a thread end 32, and, in this embodiment, a head end process 46. The head end process 46 is a projection on the head end 34 of the tension link 28. The head end process 46 may be used to prevent rotation of the tension link 28 within the hollow core 22 similar to the link retainer 44. However, this embodiment would most commonly be used with an attachment device 10 having a entry channel 26, and the head end process 46 could be placed in contact with a wall of the entry channel 26 to prevent the rotation.

With reference to Fig. 12, an embodiment of the connector 40 is shown. The connector has a receiving end 48 and a rod end 50. The receiving end 48 includes a head receptacle 42 for receiving the enlarged area 20 of the attachment device 10. The rod end 50 includes a rod aperture 52 for receiving a implant component 54, such as a spinal rod implant or other device. A tension link cavity 56 is provided from the head receptacle 42 to the rod end 50. The tension link cavity 56 is sized to allow the insertion of the thread end 32 of a tension link 28 through the connector 40. In the embodiment of the connector 40 shown in Fig. 12, a link nut recess 58 is provided at the rod end 50 adjacent to the tension link cavity 56 for seating a link nut 60 used to secure the connector 40 to the tension link 28. As shown in Fig. 12, the connector may include a gap 62 located medially between the receiving end 48 and the rod end 50, and in operative relationship with the rod aperture 52 such that when the gap 62 is closed, the rod aperture 52 may secure the implant component 54. In this embodiment, tightening of the link nut 60 on the tension link 28 closes the gap 62, and thus secures the implant component 54, concurrently with securing the connector 40 to the

Referring now to Figs. 19a and 19b, an alternative embodiment of the surgical implantation system 70 is provided. In this embodiment, a dynamic system is created wherein the implant component 54 is allowed to move freely along its longitudinal axis within connector rod aperture 52. This is accomplished by manufacturing some clearance tolerance within the rod aperture 52 when the link nut 60 is completely tightened on tension link 28. Fig. 19a also shows an alternative embodiment of a retaining recess 72 adjacent to the connector rod aperture 52. The retaining recess 72 corresponds with a retaining process 74 on the implant component 54 to limit the extent of dynamic nature within the implant. The retaining recess 72 and the retaining process 74 are sized and work in relation to one another such that the longitudinal movement of the implant component 54 is arrested when the retaining process 74 nests in the retaining recess 72.

Although it is not shown in the drawings, it is also possible to use the retaining process 74 without the retaining recess 72. It this aspect, the longitudinal movement of the implant component 54 is arrested when the retaining process 74 contacts the exterior surface of the connector 40 at the rod aperture 52. It is also possible to use either of the two above embodiments on either side of the rod aperture 52, wherein the longitudinal movement of the implant component 54 can be constrained in one or both directions.

Additional embodiments of the present invention are not shown in the drawings. For example, it is expected that the attachment device 10 may be used in conjunction with a hook in place of the tension link 28. In this embodiment, the hook would have a ball end and a hook end. The ball end would be inserted into the central core 22 of the attachment device 10 and the hook end would be used to secure some bodily structure, such as a bone. The hook rod would be capable of polyaxial movement.

The present invention also relates to a method of using the embodiments as set forth above. In one embodiment, the method using a surgical implant system 70 would first require the selective insertion of the attachment device 10 into a human bone. The tension link head end 34 could then inserted into the hollow core 22 of the attachment device 10. The step of insertion of the head end 34 would depend upon the embodiment of the attachment device 10 selected. For example, if a attachment device 10 with an entry channel 26, but no tension link slot 36, is provided, the tension link 28 is positioned in the aperture 24 by way of the entry channel 26. The connector 40 is positioned on the tension link 28 by inserting the tension link 28 through the connector tension link cavity 56.

What is claimed is:

1. A connector device adapted for use with an anchoring shaft, the anchoring shaft including an anchoring shaft head, the device comprising:

a shank having first and second ends,

said first end having a securing mechanism, and

said second end comprising a hollow core, an entry channel, and a central aperture operatively associated with said hollow core and said entry channel, wherein said entry channel is sized for receiving the anchoring shaft, and said cental aperture is sized for retaining the anchoring shaft head within said hollow core.

2. Cancelled.

3. Cancelled.

4. A connector as in claim 1, wherein said second end further comprises at least one expansion slot operatively associated with said central aperture.

5. A connector device as in claim 1, wherein said securing mechanism is selected from the group consisting of screw threads, hooks, plates, and flanges.

6. A connector device as in claim 1, wherein said hollow core has an interior surface, said interior surface having a texture.

7. A connector device as in claim 1, wherein at least a portion of the second end of said connector device has a shape selected from the group consisting of: spherical, semi-spherical, aspherical, polyhedral, conical, and a truncated cone shape.

8. A surgical implant assembly, comprising:

a connector device having first and second ends, said second end having a hollow core and a central aperture;

an anchor shaft having a proximal end and a distal end, said proximal end having an anchoring shaft head and said distal end being threaded, said anchoring shaft head insertable into said hollow core through an entry channel provided in said connected device and retained within said central aperture;

a connecting link having a connecting end with an anchoring shaft cavity said connecting link secured to said connector device by an anchoring shaft nut on said distal end of said anchoring shaft.

9. The surgical implant assembly of claim 8, further comprising:

an implant component having first and second ends, and secured to said assembly by said anchoring shaft and said anchoring shaft nut.

10. The surgical implant assembly of claim 8, wherein said implant component has a retaining process at said second end, whereby longitudinal movement of said implant component arrests when said retaining process contacts said connector.

11. The surgical implant assembly of claim 8, wherein said second end of said connector device further comprises an entry channel.

12. The surgical implant assembly of claim 8, wherein said entry channel is operatively associated with said central aperture of said second end of said connector device.

13. The surgical implant assembly of claim 8, wherein said second end of said connector device further comprises at least one expansion slot operatively associated with said central aperture.

14. A method of installing a surgical implant assembly, comprising the steps of:

(a) securing a connector device to human bone, said connector device having a shank with first and second ends, said second end able to receive an anchoring shaft and having a hollow core and a central aperture;

(b) attaching an anchor shaft, having an anchoring shaft head, to said connector device by inserting said anchoring shaft head into said hollow core such that said anchoring shaft extends through said central aperture;

(c) seating a connecting link onto said second end of said connector device such that said connector device such that said anchoring shaft extends through said anchoring shaft cavity;

(d) inserting a implant component through an aperture in said connecting link; and

(e) securing said connecting link to said connector device by threading and tightening a link nut onto said distal end of said anchoring shaft.

15. The method of claim 14, further comprising the step of adjusting an angular relationship between said connector device and said connecting link.

16. The method of claim 14, wherein said adjusting step occurs between steps (d) and (e).

17. The method of claim 14, wherein said second end of said connecting device further comprises an entry channel operatively associated with said hollow core;

said attaching step comprising inserting said distal end of said anchoring shaft through, respectively, said entry channel, said hollow core, and pulling said anchoring shaft through said central aperture until said anchoring shaft head is positioned in said hollow core.

18. The method of claim 14, wherein said second end of said connecting device further comprises an entry channel having an entrance operatively associated with said hollow core and a slot through said second end to said hollow core between said entry channel and said central aperture;

said attaching step comprising placing said anchoring shaft head at said entrance of said entry channel, inserting said anchoring shaft into said slot such that said anchoring shaft is located within said central aperture, and pulling said anchoring shaft head is positioned in said hollow core.

19. The method of claim 14, further comprising the step of securing said implant component.

20. The method of claim 14, wherein said step of securing said implant component occurs before step (e).

21. The method of claim 14, wherein said step of securing said implant component occurs after step (e).

22. (Added) A connector device as in claim 1, wherein said hollow core has an exterior surface, said exterior surface having a texture.

23. (Added) A connector device adapted for use with an anchoring shaft, the anchoring shaft including an anchoring shaft head, the device comprising:

a shank having first and second ends,

said first end having a securing mechanism, and

said second end comprising an enlarged area including at least one expansion slot, a hollow core and a central aperture operatively associated with said hollow core, wherein said enlarged area is deformable to accommodate the insertion of the anchoring shaft head through the central aperture and into said hollow core.

24. (Added) A connector device as in claim 23, further comprising a second expansion slot.

25. (Added) A connector device as in claim 24, wherein said second expansion slot is located diametrically opposite to said first expansion slot.

26. (Added) A connector device as in claim 23, wherein said second end is devoid of threads.

27. (Added) A connector device as in claim 23, wherein said securing mechanism is selected from the group consisting of screw threads, hooks, plates, and flanges.

28. (Added) A connector device as in claim 23, wherein said hollow core has an interior surface, said interior surface having a texture.

29. (Added) A connector device as in claim 23, wherein said hollow core has an exterior surface, said exterior surface having a texture.

30. (Added) A connector device as in claim 23, wherein at least a portion of the second end of said connector device has a shape selected from the group consisting of: spherical, semi-spherical, aspherical, polyhedral, conical, and a truncated cone shape.

31. (Added) A connector device adapted for use with a poly-axially adjustable connector, the connector including an anchoring shaft, the anchoring shaft including an anchoring shaft head, the device comprising:

a shank having first and second ends,

said first end having a securing mechanism, and

said second end devoid of threads and comprising an enlarged area including a hollow core adapted to receive the anchoring shaft head, and a central aperture operatively associated with said hollow core and sized for retaining the anchoring shaft head within said hollow core, wherein the anchoring shaft head is poly-axially adjustable within said hollow core.

32. (Added) A connector device as in claim 31, wherein said second end further comprises an entry channel.

33. (Added) A connector device as in claim 32, wherein said entry channel is operatively associated with said central aperture.

34. (Added) A connector device as in claim 31, wherein said securing mechanism is selected from the group consisting of screw threads, hooks, plates, and flanges.

35. (Added) A connector device as in claim 31, wherein said hollow core has an interior surface, said interior surface having a texture.

36. (Added) A connector device as in claim 31, wherein said hollow core has an exterior surface, said exterior surface having a texture.

37. (Added) A connector device as in claim 31, wherein at least a portion of the second end of said connector device has a shape selected from the group consisting of: spherical, semi-spherical, aspherical, polyhedral, conical, and a truncated cone shape.